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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,738	02/16/2001	Margret Maria Sauter	2283/201	3348

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	PAPER NUMBER
1638	16

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/785,738	SAUTER ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 04 November 2002 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) 3,9-24,30-32 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1,2,4-8,25-29 and 33-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-2, 4-8, 25-29, 31 and 33-36, and SEQ ID NO:1, in Paper No. 15, is acknowledged. The traversal is on the ground(s) that the inventions must be both independent and distinct for restriction to be proper, and on the ground(s) that the interdependence of the groups of inventions is mandated by the written description requirement which compels disclosure of all aspects of the invention. This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed inventions if they are either independent *or* distinct (MPEP § 803). This is also not found persuasive because the written description requirement does not require the disclosure of all aspects of the invention in the claims. Accordingly, claims 3, 9-24, 30 and 32, and the nonelected sequences, are withdrawn from consideration as being directed to nonelected inventions. Furthermore, as claim 31 is directed solely to nonelected sequences, claim 31 is also withdrawn as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claims 33-36 are objected to for their dependence on non-elected claim 3. Appropriate correction is required.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed July 31, 2002, Paper No. 12, is attached to the instant Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-8, 25-29, and 33-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a transgenic plant, plant cell or host cell, and a genetic construct or chimeric gene, which comprise any nucleotide sequence for any SH2A or SH2A-like gene, from any source, including the elected nucleotide sequence of SEQ ID NO:1, wherein said nucleotide sequence is heterologous to the genome of said plant.

The claims do not recite the specific identity or function of any particular SH2A nucleotide sequence or protein. Absent reference to the specific identity or function of an SH2A nucleotide sequence or protein, a critical element of the claimed invention remains undefined, such that the invention is not adequately described. In contrast, the specification describes the cDNA sequence of SEQ ID NO:1 obtained from submerged rice roots, said sequence encoding a polypeptide having an amino acid sequence of SEQ ID NO:2, and said polypeptide having amino acid sequence homology to putative proteins and ORFs of a number of ESTs corresponding to hypothetical proteins of other plants, animals, and fungi, as well as to bacterial proteins (page 42 and Figures 2, 3 and 5). The specification does not describe or characterize other DNA sequences corresponding to an SH2A or SH2A-like gene.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lily and Co., 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus including their function, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. (See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4, 6, 8, 25-29 and 33-36, and claims 5 and 7 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2, 4, 6, 8 and 25-29 are indefinite in the recitation of "SH2A or SH2A-like". It is unclear what the acronym "SH2A" designates. It is also clear in what way the protein is like SH2A.

Claims 1-2 and 33-36 are indefinite in the recitation of "essentially derived". It is unclear what characteristics of the transgenic plant would be retained by an "essentially derived" variety thereof.

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 33-36 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 33-36 are drawn to pollen, seed, a cutting, and a flower from a transgenic plant or essentially derived variety thereof, but are not limited to pollen, seed, a cutting, and a flower that comprise the construct that was introduced into the parent plant. Due to Mendelian inheritance of genes, a single gene introduced into the parent plant would only be transferred to half of the seeds of that plant. Additionally, a transgenic plant may be chimeric such that all of its cells would not comprise the transgene in question. In addition, given that there is no indication that there would be any other distinguishable characteristics of the claimed pollen, seed, a cutting, or flower, it is unclear whether they would be distinguishable from pollen, seed, cuttings and flowers that would occur in nature. See *Diamond v. Chakrabarty,* 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo Inoculant Co.*, 233 U.S. 127 (1948), and *In re Bergey*, 195 USPQ 344,

(CCPA). The amendment of the claims to recite that the pollen, seed, cuttings and flowers comprise the construct that was introduced into the transgenic plant would overcome the rejection.

Claims 1-2, 4-8, 25-29, and 33-36 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to a transgenic plant, plant cell or host cell, and a genetic construct or chimeric gene, which comprise a nucleotide sequence for an SH2A or SH2A-like gene, including the elected nucleotide sequence of SEQ ID NO:1, wherein said nucleotide sequence is heterologous to the genome of said plant.

First, the claims do not recite a specific function for the SH2A gene or the polypeptide it encodes. The claimed invention lacks utility because no specific function has been demonstrated for the polypeptide encoded by the SH2A gene. Although the specification reveals that the DNA sequence of SEQ ID NO:1 encodes a polypeptide having amino acid sequence homology to putative proteins and ORFs of a number of ESTs corresponding to hypothetical proteins of other plants, animals, and fungi, as well as to bacterial proteins, no empirical data is provided to support a function for the protein encoded by SEQ ID NO:1. While empirical data is not required for patentability, the state of the art recognizes that while a functional assignment based on sequence comparisons may categorize a protein into a particular class of proteins or provide a starting point for verifying protein activity, it does not replace empirical data for confirming protein activity, as structural homology between amino acid sequences is not always predictive of their functional homology. For example, Doerks et al. teach that incorrect or incomplete

sequence information within a database affects the predictive capacity of the database (Trends in Genetics, June 1998, Vol. 14, No. 6, pages 248-250, see page 248 column 1 paragraph 1). Doerks et al. also teach that query searches may identify shared homology with multiple groups of functionally unrelated proteins (Page 248 column 3 second full paragraph), that regions of shared homology may be nonfunctional regions (Page 248 column 3 third full paragraph), and that the degree of shared homology within a functional region does not always predict a conservation of the functional mechanism of that region (Page 248 column 3 fourth full paragraph).

Second, Applicant's claimed plants, cells and constructs lack substantial utility under current utility guidelines. While the specification implies that the SH2A gene is useful because it encodes a protein that may function to confer adaptation to hypoxic conditions when expressed in plants (Abstract), the specification does not disclose any function for the protein encoded by SEQ ID NO:1, or any adaptation to hypoxic conditions in transgenic plants or cells transformed with SEQ ID NO:1. Applicant does not teach how the claimed plants, cells and constructs would be substantially beneficial to the public. Although plants, cells and constructs comprising nucleotide sequences encoding proteins of known function may have a well established utility, plants, cells and constructs comprising nucleotide sequences encoding proteins of unknown function do not. It is apparent that extensive further research, not considered to be routine experimentation, would be required before one of skill in the art would know how to use the claimed invention. It has been established by the courts that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility.

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (Brenner v. Manson, 383 U.S. 519 (1966)).

Thus, while a plant comprising a nucleotide sequence that confers adaptation to hypoxic conditions has substantial benefit to the public, Applicant does not disclose that SEQ ID NO:1 has such an effect when expressed, and one skilled in the art cannot conclude that SEQ ID NO:1 encodes a functional protein based upon Applicant's disclosure. Applicant's invention is not refined to the point where specific benefit exists in currently available form. As set forth above, one skilled in the art cannot readily take Applicant's claimed invention and derive immediate benefits from it based upon Applicant's disclosure. Accordingly, the claimed invention lacks a real world use. (See Utility Examination Guidelines published in the Federal Register, Vol. 66, No. 4, Friday, January 5, 2001, Notices, pages 1092-1099).

Claims 1-2, 4-8, 25-29 and 33-36 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi et al. (Mammalian Genome, 1994, Vol. 5, No. 1, pages 52-54).

The claims are drawn to a host cell, including a bacterial cell, and a genetic construct or chimeric gene, which comprise a nucleotide sequence for an SH2A or SH2A-like gene, including a genomic sequence and a synthetic sequence, in the sense or antisense orientation relative to a regulatory region directing its expression.

Choi et al. teach a genetic construct or chimeric gene which comprises a nucleotide sequence for an SH2A gene obtained from a rat genomic HaeIII library established in Charon 4A (page 52 column 1 2nd paragraph). The nucleotide sequence for taught by Choi et al. would necessarily have been contained in a bacterial host cell, as the sequence was obtained from a bacteriophage library. The nucleotide sequence taught by Choi et al. would also necessarily have been in the sense or antisense orientation relative to a regulatory region directing its expression as the sequence was cloned in a bacteriophage vector. While the sequence taught by Choi et al. is not a synthetic sequence, a synthetic sequence would be indistinguishable from a naturally occurring sequence.

Remarks

No claim is allowed.

Claims 1-2, 4-5, 29 and 33-36 are deemed free of the prior art due to the failure of the prior art to teach or suggest a transgenic plant or plant cell comprising an isolated nucleic acid of SEQ ID NO:1, or a chimeric gene construct comprising SEQ ID NO:1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
January 25, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638